

PRIVILEGED AND CONFIDENTIAL
ATTORNEYS' WORK PRODUCT

May 2, 1990

DRAFT TESTIMONY BY CONSULTING SCIENTIST
ON THE KENNEDY BILL

My name is William George and I am appearing today on behalf of the six major American cigarette manufacturers to discuss scientific information relating to ingredients that are added to tobacco in the manufacture of cigarettes. Based on my consultation with the industry and a detailed review of the relevant scientific information, it is my opinion that the cigarette ingredients used by these manufacturers do not pose a risk of adverse health effects.

I am the Director of Toxicology and a full Professor in the Department of Pharmacology at the Tulane University Medical School. I am also an Adjunct Professor of Environmental Health in the Tulane School of Public Health and Tropical Medicine. I hold a Ph.D degree in Pharmacology, as well as degrees in pharmacy and chemistry. I have published widely in the fields of toxicology, biochemistry and pharmacology, and I am a member of a number of professional societies in these disciplines. My particular research interests include evaluation of carcinogenic agents, mechanisms of toxicology and assessment of environmental hazards.

202271148

During the past year, I have provided advice and consultation to the six major American cigarette manufacturers with respect to the scientific review of cigarette ingredients. As part of this process, I have been provided full access, under a confidentiality agreement, to ingredient lists submitted to HHS on behalf of the companies, ingredient use information, scientific reviews and reports, and test information on cigarette ingredients. I have also reviewed ingredient data and test results possessed by individual cigarette manufacturers, and have engaged in detailed and ongoing discussions with company scientists regarding ingredient issues. My testimony today is based on this extensive review and consultation.

Although I am not free to discuss specific ingredients or test results, I would like to explain briefly the basis for my conclusion that there is no cause for concern with respect to possible adverse health effects from cigarette ingredients.

First, I have been very favorably impressed with the strong commitment of the major American cigarette manufacturers carefully to assess the possible health effects of ingredients, with the expertise and forthrightness of the company scientists responsible for ingredients and with the quantity and quality of the test information on ingredients developed by the companies. It is against this background that my views are framed.

2022711149

Second, it is important to bear in mind that only a few cigarette ingredients comprise the great bulk of the total quantity of ingredients employed by the industry and that the vast majority of ingredients are used in very small amounts, resulting in levels of generally less than 5 parts per million (ppm) in the finished cigarette.

Although the lists of ingredients that have been submitted by the industry to HHS contain many compounds, about 20 of the ingredients comprise approximately 99% of the total amount, by weight, of ingredients used by the industry. Most other ingredients are used in much smaller amounts, in many cases only as components of flavor formulations. There may be a large number of ingredients in a particular flavor formulation, but typical industry-wide usage of most of the ingredients found in these flavors is under 10 pounds per year. This is in contrast with the over 850 million pounds of tobacco employed in cigarettes sold in the United States each year. In addition, it is important to note that processing aids, which typically are used in large amounts, are greatly reduced during the manufacturing process. Such processing aids remain in the final cigarette in minute quantities, if at all.

It is a fundamental principle of toxicology, which is frequently confirmed in my research, that toxicity is a function of dose and that many compounds are toxic at very high dose levels but not at the lower levels to which humans are ordinarily exposed. This is true of naturally occurring

2022711150

and added substances in food and equally true of the ingredients employed in cigarettes. Accordingly, the vast majority of cigarette ingredients would not be expected to raise a health concern, based simply on the minuscule amounts present in the finished product.

Third, virtually all of the ingredients used by American cigarette manufacturers are foods, normal components of foods, ingredients approved for addition to foods by the federal Food and Drug Administration (FDA) and/or expert bodies as Generally Recognized as Safe (GRAS) for human consumption, and/or normal constituents of tobacco leaf or smoke. The few ingredients that do not fall within one or more of these categories have been carefully evaluated by scientists employed by the tobacco industry and determined not to present any measurable risk under the conditions of use in cigarettes. My review of the companies' studies confirms this judgment.

The ingredients added to cigarettes which are foods, food components or GRAS ingredients have been shown to be safe for consumption as part of the human diet. The level of exposure to these ingredients in cigarettes is very low in comparison to exposure from food. The majority of cigarette ingredients, including virtually all flavors, are transferred intact in smoke and do not pyrolyze. Under these circumstances, tobacco ingredients are likely to be metabolized by smokers in essentially the same manner as when

2022711151

ingested. Given the food use of most non-tobacco ingredients employed in cigarettes, the low levels of ingredients used in cigarettes and the lack of pyrolysis of most ingredients, it is my view that smokers are not exposed to any measurable health risk from ingredients in cigarettes.

Fourth, based on my review of the ingredient lists submitted to HHS and my knowledge of the relevant scientific literature and government publications, none of the ingredients used by the companies for which I am appearing has been determined to be a carcinogen. Where questions have been raised regarding the carcinogenic potential of a substance, a careful determination has been made that the substance is not, in fact, a carcinogen. In addition, I do not believe that any of the ingredients are mutagenic or teratogenic. None of the compounds is recognized as a known teratogen. Mutagenicity tests have been conducted on a large number of cigarette ingredients. A very small percentage have tested positive in mutagenicity screening tests. Where this is the case, more extensive research has established that there is no cause to believe that the ingredient is harmful.

Finally, as I noted at the outset, the tobacco industry has an extensive program for review and testing of ingredients. Depending upon the type of substance, level of use and other factors, ingredients have been subjected to a variety of toxicity tests, including acute, subchronic and chronic studies. Each company has its own review mechanism

2022711152

for ingredients, and each has carefully selected the ingredients it uses. These decisions are made by each company individually, of course, since the identity of ingredients is an important trade secret.

Based on my consultation with the companies and review of their data, it is clear to me that the companies have carefully reviewed each ingredient and properly concluded that none of them raises health concerns. This conclusion is based upon the available scientific evidence for specific ingredients, including information from the public literature and information developed by the companies. The companies have considerable scientific resources, and have utilized those resources in a responsible manner.

I would be happy to try to answer any questions that you may have, consistent with my area of expertise and subject to the important confidentiality concerns that I have mentioned.

2022711153